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10/091,742	03/05/2002	James H. Anderson	56,492 (71699)	8190

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EXAMINER
ASHBURN, STEVEN L

ART UNIT	PAPER NUMBER
3714	

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,742	ANDERSON ET AL.	
	Examiner	Art Unit	
	Steven Ashburn	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

MARK SAGER
PRIMARY EXAMINER

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

The claims are objected to because they are incorrectly numbered. Particularly, claim 20 appears twice. As a result, all subsequent claims are misnumbered. Within this action the Applicant's numbering is retained with the exception that the examiner refers to the duplicate claims as 20(a) and 20(b). Correction is required.

Claims 44 and 46 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 44 and 46 not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). Claim 66 states, "... wherein the fluid is air." In fact, air is a gas, not a fluid. Therefore, the claim is indefinite for failing to particularly point out what is injected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Gillio, U.S. 5,704,791 (Jan. 6, 1998).

Gillio discloses a medical simulation system wherein a user controls a virtual medical device inserted into the virtual orifice. The device corresponds to a grabber, knife, laser, catheter etc. on the working channel of a scope. A tube, shaft or column with or without end deflection is inserted in a virtual orifice. Feedback is provided from one or more of the mouse, the tube or the virtual orifice, with additional feedback from the inside of the box to the computer. The computer can control the various elements of the system, and it may also perform other functions. Generally, the system provides an improved surgical training tool.

In regards to claim 38 and 64 *Gillio* teaches a syringe for simulating fluid delivery comprising:

a. a housing defining a lumen comprising an opening for delivering a fluid. *See fig. 14; col. 14:41-15:34.*

b. A pushing element for pushing the fluid through the opening. *See id.* It is implicit that a syringe handle for simulating a syringe has a pushing element for pushing fluid.

c. A friction-producing element in communication with the pushing element. *See id.*

d. A motor in communication with the friction-producing element and comprising a signal-receiving element. *See fig. 1, 14; col. 6:61-7:20, 14:41-15:34.*

e. wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation by the motor in response to a signal received by the signal-receiving element. *See id.*

Thus, the claim is unpatentable because *Gillio* anticipates every feature.

In regards to claim 39, *Gillio* additionally teaches the syringe according to claim 38, wherein the motor, when activated, causes motion of the friction-producing element, thereby causing the friction-producing element to contact the surface of the lumen of the housing, creating friction between the pushing element and the surface of the lumen and resistance to the motion of the pushing element. *See id.*

In regards to claim 40, *Gillio* additionally teaches the syringe according to claim 38, wherein the friction-producing element comprises one or more rubber pads. *See id.*

In regards to claim 41, *Gillio* additionally teaches the syringe according to claim 40, wherein each rubber pad is coupled to an arm whose movement is controlled by the motor. *See id.*

In regards to claim 42, *Gillio* implicitly teaches the syringe according to claim 41, wherein each arm is coupled to the motor through a gear attached to the motor. *See id.* The use of gears for coupling a motor to other components is of such common and notorious nature that the feature is presumed unless otherwise stated.

In regards to claim 43, *Gillio* implicitly teaches the syringe according to claim 38, wherein the amount of friction produced by the friction-producing element is adjusted by controlling a rotation angle of the motor. *See id.* The motor is only capable of angular rotation as a means of control.

In regards to claim 44, *Gillio* additionally teaches the syringe of claim 38, wherein opening of the syringe is connectable to a connecting piece having a first end for receiving fluid from the opening and second end for delivering fluid to a simulated body cavity or body lumen in the manikin. *See id.*

Claims 45 and 65-67 are rejected under 35 U.S.C. 102(b) as being anticipate by Merril, U.S. Patent 6,106,301 (Aug. 22, 2000).

Merril discloses a system for simulating the movement of surgical in the body cavity of a patient. The system provides devices for selective manipulation by a user and for providing navigation information associated with the manipulation to the interface. It is also for the transmission to the simulation system to enable it to simulate traversal of a navigation instrument via the simulated anatomy in accordance with the manipulation. The inflation peripheral is selectively manipulable by the user and associated with a navigation instrument balloon at the end of the instrument to provide information associated with the manipulation of the inflation peripheral to the interface. This is transmitted to the simulation system to enable it to simulate inflation of the balloon in accordance with manipulation of the inflation peripheral. Generally, the system enhances realism within medical procedure simulations by incorporating various peripherals in form of mock medical instruments within interface device.

In regards to claim 45 and 65 *Merril* teaches a balloon-inflating device for simulating deployment of a balloon within a body cavity or lumen of a patient, comprising:

a. A delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon. *See fig. 1-5; 5:43-57, 6:45-7:16, 14:20-16:41.*

b. A pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device. *See id.*

c. An electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. *See id.*

d. A processor for receiving the signal, the processor connectable to the network. *See id.*

e. A user device comprising an interface displaying a representation of the balloon within a simulated body cavity or lumen. *See id.*

f. Delivering the fluid to the balloon; wherein deployment of the balloon in response to the delivering is displayed on the user device. *See id.*

In regards to claim 66 *Merril* additionally teaches the injectant being air. *See id.*

In regards to claim 67, *Merril* additionally teaches the method according to claim 65, wherein the method is used to simulate balloon angioplasty. *See id.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-37, 46-63 and 69-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merril, U.S. Patent 6,106,301 (Aug. 22, 2000) in view of Gillio, U.S. 5,704,791 (Jan. 6, 1998).

In regards to claim 1, *Merril* teaches:

a. Medical device comprising a first end for manipulation by a user and a portion comprising a second end inside a housing wherein the housing.

b. Housing comprising an interface connecting the portion comprising the second end

c. Housing for interfacing with a simulated body cavity or lumen within the housing, wherein the interface comprises a directional force feedback mechanism for exerting a directional force on the medical device in response to a feedback signal received by the force feedback mechanism.

Thus, *Merril* teaches every feature of the claim except the following;

a. Housing being a manikin.

b. Medical device having a second end insertable into a simulated body cavity or lumen in a manikin and the manikin having an interface for receiving the second end.

Regardless of the deficiencies, these features were known at the time of the invention and would have been obvious to an artisan in view of *Gillio.*

First, *Merril* additionally suggests that the system's housing may be of any size or configuration suitable for containing the interface devices and peripherals. *See col. 8:64-67. Gillio* teaches that it is known in the art to provide surgical training devices in the form a manikin. *See col. 1:26-36* (incorporating by reference U.S. Pat. 4,907,973 to Hon wherein a person interacts with training device in the form of a manikin). Thus, it would have been obvious to an artisan at the time of the invention to modify *Merril*, wherein the system is simulates operations of patients, to add the feature of having the housing being in the form of a manikin and thereby increase the realism of the system. As suggested by *Gillio,* it is desirable to enchace realism of a simulated medical procedure. *See col. 5:7-14.*

Second, *Merril* teaches simulated medical instruments with a first and second end wherein the second end is insertable into a simulated body cavity or lumen in a manikin and the manikin having an interface for receiving the second end. *See fig. 1, 4, 6, 14, 15; col. 4:21-28.* Thus, it would have been

obvious to an artisan at the time of the invention to modify *Merril*, wherein a user learns to operate medical instruments inserted into an opening, to add the features medical device having a second end insertable into a simulated body cavity or lumen in a manikin and the manikin having an interface for receiving the second end. As taught by *Merril*, the modification would provide an improved means for simulating the instruments a surgeon would use in performing an actual medical procedure. *See col. 1:5-11.*

In regards to claims 2 and 52, *Merril* generally teaches a system providing tactile feedback realistically simulating the feel of medical instruments inserted into a body through a cavity in response to a feedback signal. *See fig. 1, 2; col. 5:18-7:23.* However, the reference does not explicitly teach having the directional force feedback mechanism provides resistance to forward motion but enables free reverse motion. Regardless, this feature would have been obvious to an artisan because the feature effectively claims a spring. The claim describes the tactile sensation of inserting an object into a material and removing the object from the resulting hole. It is notoriously well known in the art to use springs constants as a directional force feedback mechanism to provide directional resistance in one direction and free reverse motion in the opposite direction. Thus, it would have been obvious to an artisan at the time of the invention to modify the medical simulator suggested by the combination of *Merril* and *Gillio*, wherein tactile feedback is used to simulated the forces on medical instruments during a medical procedure, to include the feature of having the directional force feedback mechanism provides resistance to forward motion but enable free reverse motion. The feature would simulate the resistance caused by displacing material as the simulated instrument is inserted the body and corresponding lack of resistance as the simulated is pulled from the resulting hole. Notably, it would be a matter of design choice as to the amount of resistance in each direction would be required to reproduce the forces experineced of a real procedure.

In regards to claim 3, *Merril* additionally teaches a directional force feedback mechanism comprising a rolling element coupled to the portion of the device comprising the second end and wherein an internal surface of the simulated cavity or lumen in the manikin comprises an oblique slot for receiving the rolling element. *See fig. 1-3.*

In regards to claim 4, *Merril* additionally teaches, in response to a feedback signal, forward movement of the second end causes the rolling element to be received by the slot, thereby causing resistance to further forward motion. *See fig. 1-5; col. 18:28-67.*

In regards to claim 5, *Merril* additionally teaches a motor controls movement of the rolling element. *See fig. 3.*

In regards to claim 6, *Merril* additionally teaches a tactile feedback mechanism. *See fig. 1-5.*

In regards to claim 9, *Merril* additionally teaches a position of at least the second end of the medical device relative to the manikin is continuously tracked. *See fig. 1-5.*

In regards to claim 10, *Merril* additionally teaches an encoder for tracking the translation of the device and an encoder for tracking the rotation of the device. *See fig. 1-5.*

In regards to claim 11, *Merril* additionally teaches a tracking unit comprising a light source, a signal processing circuit, and one or more optical sensors, wherein the tracking unit is placed within the

interface in optical communication with the device when it is inserted into the cavity or lumen. *See fig. 1-5; 7:53-8:28, 18:28-67.*

In regards to claim 12, *Merril* additionally teaches light from the light source reflects on the device when inserted and wherein the reflected light is received by the one or more optical sensors. *See id.*

In regards to claim 13, *Merril* additionally teaches having changes in reflected light received by the one or more sensors is detected by the system, and wherein, in response to this detection, the system simulates movement of the device in real-time on the user display. *See id.*

In regards to claim 14, *Merril* suggests having two optical sensors are provided which are perpendicular to one another. *See id.*

In regards to claim 15, *Merril* additionally teaches having the tracking unit is configured in the form of a rail along which the device can move. *See fig. 1-5.*

In regards to claim 16, *Merril* additionally teaches having one or more additional medical devices comprising a first end for manipulation by a user and a portion comprising a second end for insertion into the simulated body cavity or body lumen, are inserted into the interface and wherein the position of each medical device is independently monitored. *See fig. 1-5.*

In regards to claims 17, 37, 48 and 61, *Merril* additionally suggests selecting the medical devices from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil,

balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof. *See col. 5:34-6:10, 9:35-10:32, 18:1-28.*

In regards to claim 18, *Gillio* additionally teaches placing the manikin on a table, wherein the table comprises a processor connectable to the network. *See col. 8:42-65.*

In regards to claim 19, *Gillio* additionally teaches having at least one first user device connectable to the network, the first user device comprising a first display interface for displaying a three-dimensional representation of a simulated body cavity or lumen of a patient. *See col. 1:37-55, 2:15-19.*

In regards to claim 20(a), *Merril* and *Gillio* additionally teach that a first display interface further displays a three-dimensional representation of a medical device corresponding to a medical device which is interfaced with the manikin and wherein the system simulates on the display the movement of the medical device within the simulated body cavity or lumen of the manikin in real-time when a first user manipulates the medical device interfaced with the manikin. *See Gillio col. 1:37-55, 2:15-19. See Merril, col. 5:63-6:2, 7:53-8:29.*

In regards to claim 20(b), *Merril* additionally teaches a simulated scanning display for displaying a two-dimensional image of the simulated body cavity or lumen. *See col. 7:53-8:29, 10:33-44.*

In regards to claim 21, *Merril* additionally teaches having the simulated scanning display is part of a simulated scanning device. *See id.*

In regards to claim 22, *Merril* additionally teaches having the simulated scanning device is simulating an x-ray imaging system. *See id.*

In regards to claim 23, the combination of *Merill* with *Gillio* describes all the features of the claims except having the simulated scanning device and scanning display are coupled to a movable C-arm within scanning distance of the manikin. Regardless of the deficiencies, these features were known in the art at the time of the invention and would have been obvious to an artisan. *Merril* additionally suggests incorporating further instruments in to simulate the medical procedures. *See col. 18:1-28, 19:60-20:7.* Accordingly, *Merril* incorporates a simulated display from a fluoroscope to simulate the tracking of endoscopic medical devices as they are maneuvered with a patient's body cavity. *See col. 5:63-6:2, 7:53-8:29. Gillio* suggests simulating a medical procedure by providing devices simulating the physical instruments a surgeon would use in performing an actual medical procedure. *See col. 2:36-55.* The devices could range in complexity from a simple mouse input to a full- size simulator mock-up. *See id.* In a real procedure, it is well known to employ a fluroscope mounted to a movable C-arm within scanning distance of the patient. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the simulator suggested by the combination of *Merill* with *Gillio*, wherein the simulation is a full-size mock-up of an actual procedure including a manikin, to add the feature of simulated scanning device and scanning display are coupled to a movable C-arm within scanning distance of the manikin. As suggested by *Gillio*, the modification would enhance the realism of the training system by incorporating devices a surgeon would use in performing an actual medical procedure. *See col. 2:36-55.*

In regards to claim 24, the combination of *Merill* with *Gillio* describes all the features of the claims except having a re-configurable control panel for performing one or more of: image acquisition

selection; image display; manipulating a table on which the manikin is placed; manipulating the position of a simulated scanning device relative to the manikin; and control of one or more shutter devices for limiting a field of view of a scanning device placed within scanning distance of the manikin. Regardless of the deficiencies, these features were known in the art at the time of the invention and would have been obvious to an artisan.

Merril additionally suggests incorporating further instruments in to simulate the medical procedures. *See col. 18:1-28, 19:60-20:7.* Accordingly, *Merril* incorporates a simulated display from a fluoroscope to simulate the tracking of endoscopic medical devices as they are maneuvered with a patient's body cavity. *See col. 5:63-6:2, 7:53-8:29. Gillio* suggests simulating a medical procedure by providing devices simulating the physical instruments a surgeon would use in performing an actual medical procedure. *See col. 2:36-55.* The devices could range in complexity from a simple mouse input to a full- size simulator mock-up. *See id.*

In a real procedures, it is are known to include a re-configurable control panel for performing one or more of: image acquisition selection; image display; manipulating a table on which the patient is placed; manipulating the position of a simulated scanning device relative to the patient; and control of one or more shutter devices for limiting a field of view of a scanning device placed within scanning distance of the patient. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the simulator suggested by the combination of *Merill* with *Gillio*, wherein the simulation is a full-size mock-up of an actual procedure including a manikin, to add the features a re-configurable control panel for performing one or more of: image acquisition selection; image display; manipulating a table on which the manikin is placed; manipulating the position of a simulated scanning device relative to the manikin; and control of one or more shutter devices for limiting a field of view of a scanning device placed within scanning distance of the manikin. As suggested by *Gillio*, the modification

would enhance the realism of the training system by incorporating devices a surgeon would use in performing an actual medical procedure. *See col. 2:36-55.*

In regards to claim 25, *Merril* additionally suggests a monitoring station comprising a second user device connectable to the network and comprising a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen. *See col. 7:53-8:28.* For example a display from an endoscope and a display from a fluoroscope.

In regards to claim 26, *Gillio* additionally suggests having a second display interface of the monitoring station display selectable options enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen, and wherein the selection causes the three-dimensional image of the simulated body cavity or lumen displayed to the first user to change to reflect the changed anatomical and/or physiological parameters. *See fig. 13; col. 1:1-3:26, 5:4-63.*

In regards to claims 27 and 28, *Gillio* additionally teaches having the system connectable to a database of patient images and/or medical data. *See id.*

In regards to claims 29 and 30, *Gillio* additionally teaches having patient images comprise images of a body cavity or lumen from a patient affected by a pathology. *See id.*

In regards to claim 31, *Merril* additionally suggests having one foot-activation switch for activating or collimating the simulated scanning device, image display or table movement. *See col. 6:2-5, 17:63-18:28.*

In regards to claim 33, *Gillio* additionally teaches having the user display interface provide access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the user display interface. *See col. 1:36-2:34.*

In regards to claim 34, *Gillio* additionally teaches having a user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the user display interface. *See id.*

In regards to claim 35, *Gillio* additionally teaches having user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the user display interface. *See id.*

In regards to claim 36, *Gillio* additionally teaches having user display interface provides a selectable option enabling a user to display the image displayed on the user display interface. *See id.*

In regards to claim 46, *Merril* additionally teaches the balloon-inflating device of claim 45. *See fig. 1-5; 5:43-57, 6:45-7:16, 14:20-16:41.*

In regards to claim 47, *Merril* additionally teaches the system to claim 20, wherein the system simulates deformation of the body cavity or lumen by the medical device. *See col. 16:11-41.*

In regards to claim 49, *Merril* additionally teaches system according to claim 20, wherein the system simulates the movement of the device within a blood vessel. *See col. 15:16-22, 16:33-42, 17:27-31.*

In regards to claims 50 and 51, *Merril* additionally teaches simulating the movement of the movement of devices through blood vessels to simulate minimally invasive medical procedures. *See fig. 1-5; 5:43-57, 6:45-7:16, 14:20-16:41.* It teaches that it is known in the art to perform procedures on the heart. *See col. 1:32-56.* However, the reference does not describe performing the procedure with in blood vessels within the brain. Regardless, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the system to simulate the movement of devices within the brain, to allow users to practice performing minimally-evasive procedures on simulations of these organs. As suggested by *Merril,* the modification would allows users to gain skills necessary to perform procedures without requiring practice an a real patient and thereby avoid serious injury. *See col. 1:32-2:36.*

In regards to claim 53, *Gillio* additionally teaches the method according to claim 52, further comprising providing a system comprising a processor in communication with the directional force feedback mechanism, the processor connectable to the network; a first user device in communication with the processor, the first user device comprising a first display interface for displaying a representation of a body cavity or lumen; and for providing access to a database of three-dimensional images of body cavities and lumens from a plurality of different patients; and enabling a user to select from the database a representation, wherein in response to the selection, the representation is displayed on the first display interface. *See col. 4:15-5:58.*

In regards to claim 54, *Gillio* additionally teaches the method according to claim 52, wherein the first display interface a displays a three-dimensional representation of the medical device and wherein the system simulates the movement of the medical device within the body cavity or lumen in real-time as a first user manipulates the medical device which is interfaced with the manikin. *See id.*

In regards to claims 55 and 56, *Gillio* additionally teaches all the features of the claims except a monitoring station comprising a second display interface wherein the second display interface provides a second user with access to the database and wherein when a second user selects a representation from the database, the representation is displayed on both the first and second display interface. Regardless, it is notoriously well known in the art to provide interactive monitoring stations allowing selection of simulation options and viewing of displays seen by the primary user to allow observation and control by instructors . Consequently, in this case, it would have been obvious to an artisan at the time of the invention to modify the simulation system described by the combination of *Merril* with *Gillio* to add the feature of a monitoring station comprising a second display interface wherein the second display interface provides a second user with access to the database and wherein when a second user selects a representation from the database, the representation is displayed on both the first and second display interface to allow an instructor to observer and interact with the simulation.

In regards to claim 57, *Gillio* additionally teaches the method according to claim 53, wherein the system simulates the deformation of a body cavity or lumen in response to movement of the medical device by the first user and displays the representation of the deformation on the first display interface.

In regards to claim 58, *Merril* additionally teaches the method according to claim 53, wherein the medical device performs an operation on the simulated body cavity or lumen and the first display interface displays a simulation of the operation. *See col. 17:17-60.*

In regards to claim 59, *Merril* additionally teaches the method according to claim 58, wherein the operation is inflation or deflation of a balloon within the simulated body cavity or lumen. *See id.*

In regards to claim 60, *Merril* additionally teaches the method according to claim 58, wherein the operation is injection of a radioopaque fluid within the body cavity or lumen.

In regards to claim 62, *Merril* additionally teaches the method according to claim 54, wherein a first user inserts one or more additional medical devices into the simulated body cavity or lumen, and the movement of each medical device is independently monitored. *See fig. 1-5.*

In regards to claim 63, *Merril* additionally teaches providing the system according to claim 1, inserting a balloon catheter into the simulated body cavity or lumen to simulate navigating to a target region of the body, and simulating positioning the balloon deployment device in proximity to the balloon catheter to inflate or deflate the balloon. *See fig. 1-5; col. 5:34-6:14; 6:66-7:11, 8:5-29, 10:20-67.*

In regards to claim 69, *Merril* additionally teaches the method according to claim 67, further comprising inserting a catheter and guidewire into the body cavity or lumen to navigate the balloon cavity to the target region. *See id.*

In regards to claim 70, *Merril* additionally teaches the method according to claim 67, further comprising inserting a stent catheter to navigate to a target region and using the balloon to deploy the stent, thereby simulating stent deployment in the body cavity or lumen. *See id.*

In regards to claim 71, *Merril* additionally teaches the method according to claim 68, further comprising inserting a catheter or guidewire into the body cavity or lumen to navigate the stent catheter to the target region. *See id.*

In regards to claim 72, *Merril* additionally teaches providing a catheter, guidewire and coil wire comprising a coil to navigate to a target region of the body; providing the system according to claim 19, wherein the re-configurable control panel provides a selectable option for detaching the coil from the coil wire, and wherein selecting the selectable option triggers the release of the coil from the coil wire. *See id.*

In regards to claim 73, *Merril* implicitly teaches the method according to claim 72, wherein an electrical current triggers release of the coil from the coil wire.

Claims 7, 8 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Merill* in view of *Gillio,* as applied to claims 1-6, 9-37, 46-63 and 69-73 above, and further in view of Goto et al., U.S. Patent 6,231,444 B1 (Mar. 15, 2001).

The medical simulation system suggested by the combination of *Merill* with *Gillio* describes all the features of the claims except having the tactile feedback mechanism providing continuous vibration feedback to a user holding the medical device wherein the continuous vibrational feedback is provided

through a continuously rotating motor. Regardless of the deficiencies, these features were known in the art at the time of the invention and would have been obvious to an artisan in view of *Goto*.

Merril generally teaches a system providing tactile feedback realistically simulating the feel of medical instruments inserted into a body through a cavity in response to a feedback signal. *See fig. 1, 2; col. 5:18-7:23.* Realistically, living bodies inherently constantly vibrate due to constant metabolic processes such as respiration and circulation.

Goto discloses an analogous controller device wherein a tactile feedback mechanism providing continuous vibration feedback to a user holding the medical device wherein the continuous vibration feedback is provided through a continuously rotating motor. *See fig. 19, 20; col. 12:8-37.* The reference teaches that the vibration enhances the feeling of simulated reality. *See id.*

In view of *Goto*, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify medical simulation system suggested by the combination of *Merill* with *Gillio*, wherein tactile feedback is provided by motors in communication with the second end of a simulated medical device, to add the feature of tactile feedback mechanism providing continuous vibration feedback to a user holding the medical device wherein the continuous vibrational feedback is provided through a continuously rotating motor to enhance the realism of the simulation by simulating the constant vibration caused by a patient's respiration and circulation. As suggested by *Merril*, it is desirable to enhance the simulation of reality to increase the effectiveness of training. *See col. 5:7-14.*

Conclusion

The following prior art of record is not relied upon but is considered pertinent to applicant's disclosure:

- U.S. Patent 6,470,207 B1 (Oct. 22, 2002) discloses a method for performing surgical procedures on a patient situated on a table wherein a fluoroscopic C-arm imager is employed to generate a database of imagers used to assist a surgeon in planning and executing a procedure.

- U.S. Patent 5,791,907 (Aug. 11, 1998) discloses an interactive display system for training surgeons to perform minimally invasive surgical procedures.

- U.S. Patent 5,836,869 (Nov. 17, 1998) discloses an imaging tracking system for an endoscope.

- U.S. Patent 5,261,404 (Nov. 16, 1993) discloses a system for providing a 3-D image for an endoscope.

- Frances Forest et al., *High level simulators in medical education*, Hospital Medicine, Aug. 1998, Vol. 59, No. 8, pp. 653-655, teaches using high-level simulators for training wherein a procedure is fully simulated including having multiple users interact with a manikin.

- *Project on Image Guided Surgery*, <http://splweb.bwh.harvard.edu:8000/pages/papers/-image.guided.surg2/> downloaded from the internet on Dec. 19, 2002, pp. 1-10, discloses a high-fidelity simulation of minimally invasive surgery.

- Jody Henry, *The Simulation Development and Cognitive Science Lab*, <http://hmc.psu.edu/-simlation/index.html> (1999), downloaded from the internet on Dec. 19, 2002, pp. 1-22, describes various surgical training systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Ashburn whose telephone number is 703 305 3543. The examiner can normally be reached on Monday thru Friday, 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 703-308-1806. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872 9302 for regular communications and 703 872 9303 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1078.

S.A.
December 23, 2002

MARK SAGER
PRIMARY EXAMINER